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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/381,561 09/17/99 JACKSON

J 2426-1-001

EXAMINER

HM12/0209

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PHAM, M

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

02/09/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/381,561

Applicant(s)

JACKSON, JAMES RICHARD

Examiner

Minh-Quan K. Pham

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 1 and 4 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
 2. ☐ received in Application No. (Series Code / Serial Number) ____.
 3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892) 17) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 18) ☐ Notice of Informal Patent Application (PTO-152)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 19) ☐ Other: _____

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DETAILED ACTION

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Drawings

The drawings are objected to because the figures are not correctly labeled. Correction is required.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Objections

Claims 1 and 4 are objected to because of the following informalities:

- A. Regarding claim 1, the semicolon on line 3 should be a comma.
- B. In claim 1, there should be a comma following the word "conduit" in line 4.
- C. Regarding claim 4, the word "retro-fit" should be amended to --retrofit--.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 are vague and indefinite. The recitation of "adapted to" in both claims is not clear as to how each part is modified to perform the required function.

The recitation of "selectively sized and shaped" in claim 2 renders the claim vague and indefinite. It is not clear how the device is "sized and shaped". Further, the factors that determine the size and shape of the device are not specified.

The recitation of "and/or" in claims 2, 15, and 17 renders the claims indefinite because it is not clear what is included or excluded by the claims.

Claim 2 recites the limitation "recording part" in line 2. There is insufficient antecedent basis for this limitation in the claim.

The recitation of "same" renders claim 2 indefinite because it is not clear what "same" refers to.

Claims 3 and 5-6 recite the limitation "said recording part" in lines 1-2 of each claim. There is insufficient antecedent basis for this limitation in the claims.

Regarding claim 3, the word "means" is preceded by the word(s) "electronic" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is

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impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claims 7 and 11 recites the limitation "said assay part" in lines 1 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 9, the word "suitable" is redundant.

Claim 9 is indefinite because it is not clear from the specification what the "reagents suitable for diluting said sample fluid" are.

Claim 18 recites the limitation "the data" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: step(s) to generate a data set so that it can be recorded. The claim lacks at least a detection step after mixing the sample with the reagents.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al. (US Pat. 4,756,884 and 4,963,498) in view of Galen et al. (US Pat. 5,695,949) or Phillips et al. (US Pat. 5,179,005 and 5,426,032).

Hillman et al. disclose a capillary flow device for analysis comprising a capillary and sample wells where the sample passes along the capillary and reacts with one or more reagents (see Figures 1 and 3; column 3, lines 57-62; column 4, lines 1-4 and 14-19; and column 6, lines 28-31) to produce a detectable signal. The reagents may be supply within the capillary by binding to the surface, whereby they may become dissolved in the fluid or may remain fixed to the surface (see column 6, lines 59-66). The device can have more than one capillary wherein each capillary may contain different reagents (see column 7, lines 32-47). Detection of the assay may be accomplished through the use of a detector such as a spectrophotometer, measurements of light scatter, etc.(see column 8, lines 6-59).

Hillman et al., however, differ from the claimed invention because they do not disclose an electronic recording device in data communication with the assay device.

Galen et al. disclose a detector for glucose concentration wherein the output of the detector is processed by a microprocessor which serve the following functions: calculate analyte level, output analyte level to the display, and store data (see column 13, lines 15-59; and Figures 3b and 4).

Phillips et al. disclose a detector (a spectrophotometer) for the detection of analytes wherein the detector comprises a microprocessor which serves the following functions: system timing, reading of the out put from the spectrophotometer, program and data storage, calculation

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of analyte concentration, and outputting the analyte concentration data to the display (see column 8, lines 27-65; and Figures 2-4).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the detector of Galen et al. or Phillips et al. in the device of Hillman et al. because the microprocessor has the well known advantage of large memory storage capacity and fast data processing.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Allen et al. (US Pat. 5,837,546) is cited to show a sample strip mated to an electronic detector to detect an analyte wherein the detector comprises a processor to convert the electrical signal to digital output and to store data.

Wilding et al. (US Pat. 5,726,026 and 5,637,469) are cited to show capillary devices for chemical analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.
February 7, 2000



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 / 641